

INTERNATIONAL SEARCH REPORT

International application No

PCT/IL04/01 119

A CLASSIFICATION OF SUBJECT MATTER

IPC(7) A61K 38/02, 28, 39, C07K 2/00, 14/62, 78, A61N 1/00, 30

US CL 514/2, 12, 3, 530/350, 300, 303, 356, 604/20, 501, 607/152

According to International Patent Classification (IPC) or to both national classification and IPC

B FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U S 514/2, 12, 3, 530/350, 300, 303, 356, 604/20, 501, 607/152

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
X -- Y	US 6,490,482 B2 (MORI et al) 3 December 2002 (03 12 2003), col 2, lines 13-25, col 5, lines 23-67, col 6, lines 1-67, col 10, lines 7-26, col 3, line 15, to col 4, line 61, col 9, lines 6-11, col 9, line 48, to col 10, line 26, Figs 2-3	1-5, 8, 10-13, 20-24, 26, 28-33 ----- 6, 7, 9, 15, 17, 19, 25, 27
X -- Y	US 5,961,482 (CHIEN et al) 5 October 1999 (05 10 1999), col 1, lines 18-32, col 3, lines 5-63, col 2, lines 23-61, col 6, lines 11-23, col 8, lines 4-27, col 12, lines 35-41, col 13, lines 27-41, col 12, line 51, to col 13, line 41, Figs 2-9	1-5, 8, 10-13, 20-24, 26, 28-33 ----- 7, 9, 15, 17, 19, 25, 27
Y	Nave, Electromagnetic Spectrum, HyperPhysics website of Georgia State University, http://hyperphysics.phy-astr.gsu.edu/hbase/ems2.html , printed on November 1, 2005	4
Y	US 5,418,222 (SONG et al) 23 May 1995 (23 05 1995), col 1, line 13, to col 2, line 44	7, 9, 15, 17, 19, 25, 27
Y	US 2003/0143274 A1 (VIEGAS et al) 31 July 2003 (31 07 2003), paragraphs 26, 27, 32, 37, 2, 19, 62 and 69	7, 9, 15, 17, 19, 25, 27
Y	US 5,543,098 (MYERS et al) 6 August 1996 (06 08 1996), col 6, lines 8-17, col 10, lines 13-49	7, 9, 15, 17, 19, 25, 27

☐ Further documents are listed in the continuation of Box C☐ See patent family annex

* Special categories of cited documents

A document defining the general state of the art which is not considered to be of particular relevance

E earlier application or patent published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure use exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents such combination being obvious to a person skilled in the art

& document member of the same patent family

Date of the actual completion of the international search

02 November 2005 (02 11 2005)

Date of mailing of the international search report

14 DEC 2005

Name and mailing address of the ISA/US

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Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons

- 1 ☒ Claims Nos
because they relate to subject matter not required to be searched by this Authority, namely
- 2 ☐ Claims Nos
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically
- 3 ☐ Claims Nos
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows
Please See Continuation Sheet

- 1 ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims
- 2 ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of any additional fees
- 3 ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos
- 4 ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims, it is covered by claims Nos 1-13,15,17 and 19-32

- Remark on Protest
- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee
 - ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation
 - ☐ No protest accompanied the payment of additional search fees

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BOX III OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-13, 15, 17 and 19, 20 and 22-32, drawn to a patch for transdermal delivery of an active agent, or a system composing the patch and an apparatus capable of generating a microchannel in the skin of a subject wearing the patch, wherein the active agent is insulin.

Group II, claim(s) 1-12, 14, 16, 18, 20 and 22-32, drawn to a patch for transdermal delivery of an active agent, or a system comprising the patch and an apparatus capable of generating a microchannel in the skin of a subject wearing the patch, wherein the active agent is growth hormone.

Group III, claim(s) 1-12, 20, 22-30 and 32, drawn to a patch for transdermal delivery of an active agent, or a system comprising the patch and an apparatus capable of generating a microchannel in the skin of a subject wearing the patch, wherein the active agent is selected from one of the agents in claim 12 and is not insulin or growth hormone.

Group IV, claim(s) 34-43, 45, 47 and 49 and 50, drawn to a method for sustained transdermal delivery of a therapeutic or immunogenic agent, wherein the agent is insulin.

Group V, claim(s) 34-42, 44, 46, 48 and 50, drawn to a method for sustained transdermal delivery of a therapeutic or immunogenic agent, wherein the agent is growth hormone.

Group VI, claim(s) 34-42 and 50, drawn to a method for sustained transdermal delivery of a therapeutic or immunogenic agent, wherein the agent is selected from one of the agents in claim 42 and is not insulin or growth hormone.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The requirement of unity of invention is not fulfilled because there is no technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Therefore, a technical relationship is lacking among the claimed inventions involving one or more special technical features. The technical feature that links the groups of inventions is a patch for transdermal delivery of an active agent, wherein the patch comprises a polymeric matrix and a therapeutic or immunogenic agent, and an apparatus that generates a microchannel in the skin of a subject wearing the patch.

The inventions of Groups I-VI do not share the common special technical feature of a patch for transdermal delivery of an active agent, wherein the patch comprises a polymeric matrix and a therapeutic or immunogenic agent, and an apparatus that generates a microchannel in the skin of a subject wearing the patch, because Henley (US 5,658,247) discloses a patch for transdermal delivery of a therapeutic polypeptide, such as insulin, the patch comprising electrodes for generating microchannels in the skin. The electrodes are connected to a controller (see col. 5, lines 4-48, and col. 7, lines 35-48). The patch comprises a layer of a polymer such as polyethylene, paper or cotton as a porous drug reservoir (see col. 6, lines 15-22).

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Thus, the technical feature of a patch for transdermal delivery of an active agent, wherein the patch comprises a polymeric matrix and a therapeutic or immunogenic agent, and an apparatus that generates a microchannel in the skin of a subject wearing the patch does not define the invention over the prior art. Because the common special technical feature is not novel with respect to the cited reference, it is clear that the claims of Groups I - VI lack a single common technical feature that defines them over the prior art.

Further, an international application containing claims to different categories of inventions will be considered to have unity of invention if the claims are drawn only to one of certain combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product, or
 - (2) A product and process of use of said product, or
 - (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product, or
 - (4) A process and an apparatus or means specifically designed for carrying out the said process, or
 - (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process (see 37 CFR 1.475(b)-(d)).
- In the instant case, the claims are drawn to multiple products and processes, only a particular combination of which may be considered for unity of invention, i.e., Group I and Group IV, (the first named product and the first named process of using the product). Other groups are drawn to additional products and processes, and other combinations do not comply with the aforementioned Rules. But, because a corresponding special (novel) technical feature is not present, Groups I and IV cannot be considered to have unity of invention.

Accordingly, a holding of lack of unity of invention is proper.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

- a) each one of the classes of active agent in claim 11 (the election in claim 11 will be applied to claims 29 and 41), and
- b) each one of the active agents in claim 12 (the election in claim 12 will be applied to claims 30 and 42).

Applicant is required, in reply to this action, to elect a single species in each of parts a) and b) above. The election in part b) must be consonant with the election in part a). For example, if "growth factor" is elected in a), a growth factor, such as insulin-like growth factor-1, must be elected in part b). An agent that is not a growth factor, such as thrombin, may not be elected.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons. Pursuant to PCT Rule 13.2 and PCT Administrative Instructions, Annex B, Part 1(f)(1)(B)(2), the species are not art-recognized equivalents. For example, claims 12, 30 and 42 recite a large and disparate group of compounds, each member of which is chemically, structurally and functionally distinct.

Because the claimed species are not art-recognized equivalents, a holding of lack of unity of invention is proper.

Note

Claims 21, 33 and 51 are unsearchable because they are improper multiple dependent claims.

Continuation of B. FIELDS SEARCHED Item 3

USPAT, USPGPUB, EPO, JPO, DERWENT, STN/CAS- CAPLUS, BIOSIS, search terms: patch, transdermal, electrode, electroporation, microchannel, protein, peptide, polymer, collagen, carrageenan, polyethylene